Date Prepared: 8/11/2013

510k Number: To be determined

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MAY 13 2014

Section 5

Premarket Notification 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with requirements of 21 CFR Part 807 and FDA Guidance Document *"Format for Traditional and Abbreviated 510(k)s"*

Submitters Name and Address:

Zuma Dental, LLC
2775 San Nicolo Lane
League City, TX 77573
Contact Person: Ekram Khan
Tel: (973) 703-4437

Device Name:

- Trade Name - Z-Ray Intra-Oral Digital Radiography System
- Common Name – Digital Dental X-ray System
- Classification Name – Extra-oral source x-ray system

Regulatory Classification:

Class II, per 21 CFR 872.1800
Product Code: MUH

Devices for Which Substantial Equivalence is claimed:

- Schick Computed Oral Radiography System (K072134)
- Dexis Sensor (K090458)

Device Description:

The Zuma Dental Z-ray x-ray image sensor is a fully integrated CMOS photodiode array specifically designed for dental radiography. The sensor is available in two image sizes that correspond to a #2 size and a #1 size dental film. Each consists of a matrix of silicon photodiodes on 22.5 µm centers. An integrated scintillator screen converts x-ray photons to visible light sensed by the silicon photodiodes.

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Device Description cont.:

A rugged thermoplastic enclosure, with rounded corners for patient comfort, protects the sensor from everyday handling and cleaning.

The CMOS sensor connects directly to a USB/PC connection without the need for an intermediate electrical interface. Zuma Z-Ray works with standard dental extra-oral x-ray sources without connection to the x-ray source. Zuma Z-Ray captures an image automatically upon sensing the external x-ray source and after completion of the x-ray procedure, transfers the image to an imaging software program on the PC for diagnostic evaluation.

Intended/Indications for Use:

The Z-Ray digital radiography system was designed for the sole purpose of capturing radiographic images of teeth and the surrounding structures limited to the oral cavity. This device should be used under the direction of a licensed Dentist when it is deemed necessary to perform a radiographic series of a patient for diagnostic purposes.

Statement of Substantial Equivalence:

The technological characteristics of the Zuma Dental Z-Ray System is essentially the same as the referenced predicate devices with respect to intended use, design, materials and operating characteristics. Minor technological differences do not raise any new questions regarding the safety or effectiveness of the device.

Comparison Table:

The following table compares the technological characteristics between the Zuma Z-Ray System and the referenced predicate devices, Schick Computed Oral Radiography System (K072134) and the Dexis Sensor (K090458).

Date Prepared: 8/11/2013

510k Number: To be determined

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Comparison to Predicate Devices:

Parameter	Z-Ray 510k #: TBD	Schick CDR System (K072134)	Dexis Sensor (K090458)
Indications for Use	The Z-Ray digital radiography system was designed for the sole purpose of capturing radiographic images of teeth and the surrounding structures limited to the oral cavity. This device should be used under the direction of a licensed Dentist when it is deemed necessary to perform a radiographic series of a patient for diagnostic purposes.	The Computed Oral Radiology System is intended for intra-oral x-ray examinations and indicated for dental patients. It produces instant, digital intra-oral x-ray images of a patient's mouth while reducing the necessary x-ray dosage.	The Dexis sensor is a USB-driven digital sensor which is intended to acquire dental intra-oral radiology images. The Dexis sensor shall be operated by healthcare professionals who are educated and competent to perform the acquisition of dental intra-oral radiographs. The Dexis sensor can be used either in combination with special positioning devices to facilitate positioning and alignment with the x-ray beam or it may also be positioned by hand with the assistance of a patient.
Number of Sensors	2	3	1
Sensor size (mm) Active Area	32.6 x 20.5mm 36 x 27mm	31 x 22mm 37 x 24mm 43 x 30mm	30 x 39mm
Sensor Technology	CMOS	CMOS	CMOS
System Technology	Computed Direct Radiography	Computed Direct Radiography	Computed Direct Radiography
Interface to PC	USB	USB	USB
Data Box Connection to PC	Standard USB Cable	Standard USB Cable	Standard USB Cable
Power Supply	Powered through USB connection	Powered through USB connection	Powered through USB connection
Dynamic Range	4096:1	4096:1	16,384:1
Image Capture S/W Req'd	Yes	Yes	Yes
Sensor Cable Length (m)	2.0m	2.0m	2.8m

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Safety and Effectiveness Information:

Summary of Non-Clinical Tests and Evaluations Performed:

Electrical, mechanical and performance safety testing and evaluations were conducted in accordance with ANSI/UL 60601-1 Standard for Safety, Medical Electrical Equipment, Part 1 and, IEC 60601-1-2, Medical Electrical Equipment – Part 1 – 2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests. All test results were satisfactory.

Non-Clinical considerations were conducted in accordance with FDA Guidance *"Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices, Section VI"*. All test results were satisfactory.

The software of the Zuma Z-Ray System has been validated according to FDA *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* and applicable requirements contained in the guidance document.

Summary of Bench Test:

In-vitro bench testing was conducted according to FDA Guidance *"Format for Traditional and Abbreviated 510(k)s, Section 18, Performance Testing – Bench"*. Results of the bench testing confirmed substantial equivalence in performance between the Zuma Z-Ray System and the predicate device Schick CDR (K072134) included in the test protocol for comparison evaluation. The qualified examiners concluded and certified that the diagnostic images produced by the Z-Ray System are equivalent to those produced by the predicate device.

The Zuma Z-Ray System was also tested at varying external x-ray source exposure parameters and found to continually produce diagnostic quality images as concluded by the examiners.

Date Prepared: 8/11/2013

510k Number: To be determined

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Conclusion:

Based on analyzing the device characteristics, bench-test, safety and non-clinical testing to applicable standards, it is the conclusion of Zuma Dental, LLC that the Z-Ray Digital Imaging System is as safe and effective as the referenced predicate devices. The Z-Ray system has minimal technological differences compared to the legally marketed predicate devices and is safe and effective for its intended use as well as substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 13, 2014

Zuma Dental, LLC
% Albert Rego, Ph.D.
Regulatory Consultant
27001 La Paz Road, Suite 312
MISSION VIEJO CA 92691

Re: K133206
Trade/Device Name: Z-Ray Intra-Oral Digital Radiography System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: April 12, 2014
Received: April 16, 2014

Dear Dr. Rego:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

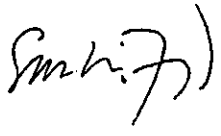
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133206

Device Name
Zuma Dental Z-Ray Intra-Oral Digital Radiography System

Indications for Use *(Describe)*

The Z-Ray digital radiography system was designed for the sole purpose of capturing radiographic images of teeth and the surrounding structures limited to the oral cavity. This device should be used under the direction of a licensed Dentist when it is deemed necessary to perform a radiographic series of a patient for diagnostic purposes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*